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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/202,054 | 12/07/1998 | AUDREY GODDARD | P1154R2 | 2403 |

7590 11/25/2005

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EXAMINER

SPECTOR, LORRAINE

ART UNIT PAPER NUMBER

1647

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/202,054

Applicant(s)

GODDARD ET AL.

Examiner

Lorraine Spector, Ph.D.

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 28-30, 48-50 and 54-57 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 28-30, 48-50 and 54-57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 28-30 and 48-50 and 54-57 are pending and under consideration. There have been no amendments to the claims.

Applicants arguments filed 9/12/2005 are largely repetitive of previous arguments, which have not been found persuasive for reasons of record. Only new grounds of argument will be responded to herein.

Claim Rejections - 35 USC § 101 and §112, first paragraph

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 28-30, 48-50 and 54-57 rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility, for reasons of record in the previous Office Action mailed 9/16/2002 at pages 2-4.

Applicants reiterate that the Jurk reference demonstrates that PRO285 stimulates via NF-K β activation. This argument has been fully considered but is not deemed persuasive because it remains that although such was mere conjecture at the time the invention was made, that stimulation or inhibition of NF-K β activation *via PRO285* has no known utility. It remains that inhibition of PRO285 will *not* inhibit NF-K β activation *unless* that activation was occurring through stimulation of PRO285 in the first place. It remains that while it is true that inhibiting or stimulating NF-K β activation may have utility under certain circumstances, those circumstances are predicated on knowledge of involvement of the particular receptor that stimulates such signaling in a biological process such as septic shock or warts. No such correlation has been disclosed for PRO285, and the discovery of such a correlation is considered to be part of the inventive process. The involvement of IL-1, -6 or -8 in the formation of warts, or in septic

shock, is not predictive of the involvement of PRO285 in the same conditions. It remains that while it is true that inhibiting or stimulating NF-K β activation may have utility under certain circumstances, those circumstances are predicated on knowledge of involvement of the particular receptor that stimulates such signaling in a biological process such as septic shock or warts. No such correlation has been disclosed for PRO285, and the discovery of such a correlation is considered to be part of the inventive process.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 28-30, 48-50 and 54-57 rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Applicants arguments of this rejection have been fully addressed above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 28 and 48 remain rejected under 35 U.S.C. 102(b) as being anticipated by Ruggeri et al., WO 91/09614.

Ruggeri et al. disclose a 19 residue peptide that matches SEQ ID NO: 2 at positions 704-712, a 9/15 match; see the third peptide listed in claim 1. At page 19 and in claim 65, antibodies to such peptides are disclosed and claimed.

Applicants arguments filed 9/12/2005 have been fully considered but are not deemed persuasive. Applicants argue that Ruggieri “fails to provide a disclosure which places one in possession of the invention” for the following reasons:

a) Ruggieri fails to provide a disclosure that allows one to discern whether antibodies raised against the platelet membrane glycoprotein Ib polypeptide will bind to a “completely different protein”. This argument has been fully considered but is not deemed persuasive because PRO285 is *not* a “completely different protein, but rather shares 9 contiguous amino acids of a 19-residue long polypeptide. There is evidence of record, “Exhibit C” submitted by applicants in a previous response, that shows that the person of ordinary skill in the art would expect antibodies to Ruggieri’s peptide to bind to PRO285. Applicants have provided no fact or evidence to the contrary.

b) Ruggieri fails to teach the three dimensional structure of the antibody binding sites on the 19-mer. This argument has been fully considered but is not deemed persuasive because there is evidence of record, “Exhibit C” submitted by applicants in a previous response, that shows that the person of ordinary skill in the art would expect antibodies to Ruggieri’s peptide to bind to PRO285. Applicants have provided no fact or evidence to the contrary.

c) Applicants argue that the examiner is using mere “conjecture” to make the rejection. This is plainly false. Ruggieri et al. disclose a 19 residue peptide that matches SEQ ID NO: 2 at positions 704-712, a 9/15 match; see the third peptide listed in claim 1. At page 19 and in claim 65, antibodies to such peptides are disclosed and claimed. The sole evidence of record indicates that it would be more likely than not that antibodies to that peptide would meet the claim limitations. Ruggieri places those antibodies in the hands of the public. It is undisputed that disclosing a 19-mer and the desirability of making antibodies to such fairly places such antibodies in the hands of the public. The burden has been properly shifted to applicants to show, using *facts or evidence*, that the inherent properties are *not* possessed by the antibodies disclosed by Ruggieri.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 29 and 49 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO 91/09614, in view of Coughlin, U.S. Patent Number 5,256,766 for reasons of record. Applicants argument of Ruggeri is found not persuasive, for reasons cited above. Applicants have presented no separate argument of the obviousness rejection.

Claims 50 and 54 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Ruggeri et al., WO 91/09614, in view of Coughlin, U.S. Patent Number 5,256,766, and further in view of U.S. Patent Number 4,946,778 (Ladner et al.) for reasons of record. Applicants argument of Ruggeri is found not persuasive, for reasons cited above. Applicants have presented no separate argument of the obviousness rejection.

Conclusion

No claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

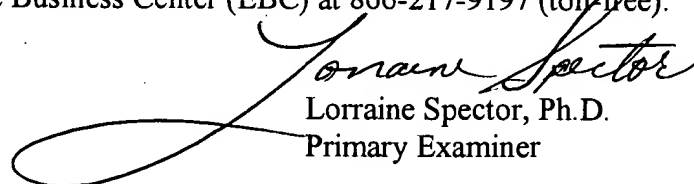
Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. *Effective 1/21/2004, Dr. Spector's telephone number is 571-272-0893.*

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). **NOTE:** If Applicant does submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. **NO DUPLICATE COPIES SHOULD BE SUBMITTED** so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to (703) 872-9306 (before final rejection) or (703)872-9307 (after final). Faxed draft or informal communications with the examiner should be directed to **571-273-0893**.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Lorraine Spector, Ph.D.
Primary Examiner

11/23/2005